

## Evaluation and Certification for Excipient GMP Conformance

IPEA grants certification of an excipient manufacturing site for substantial conformance to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients for excipients stated on the application. The duration of the certification is 24 months from the date of approval. This certification applies to the quality system and does not extend to the excipient and its conformance to monograph requirements or excipient manufacturer's specifications.

Figure 1 illustrates the process for Excipient GMP Conformance Certification.

Manufacturers of excipients apply to IPEA for Excipient GMP Conformance Certification to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients. There are no pre-conditions prior to applying for certification other than to have an established GMP quality system with documents that describe its operation and records that show conformance. However, the manufacturer must:

- a. Allow IPEA to audit their site of manufacture including any site where related GMP quality system activities are conducted, such as a contract laboratory, packaging facility, or warehouse,
- b. Agree to notify IPEA of changes that may affect their quality system, and
- c. Agree to make payment of all fees related to the assessment.

The applicant submits the completed application to IPEA and upon acceptance a Certification Agreement is prepared.

After the applicant executes the Certification Agreement and remits the non-refundable deposit, IPEA assigns qualified auditors.

The applicant is informed by IPEA of the names of the audit team members and can request a replacement auditor if they perceive the auditor may have a bias or conflict of interest.

The audit is planned and conducted. The Lead Auditor submits the draft audit report to IPEA Executive Management for review and comment. IPEA then sends the draft audit report to the applicant for review and comment. If the report contains significant adverse findings, the applicant must submit a corrective or preventive action plan. Once comments from the manufacturer have been addressed by the Lead Auditor and/or IPEA Executive Management, the final report and corrective action plan are submitted to the Certification Board.

The Certification Board reviews the application, report and corrective measures provided by the applicant. The Board considers certification based upon established criteria.

If the Certification Board rejects the application for Certification, the applicant can appeal.

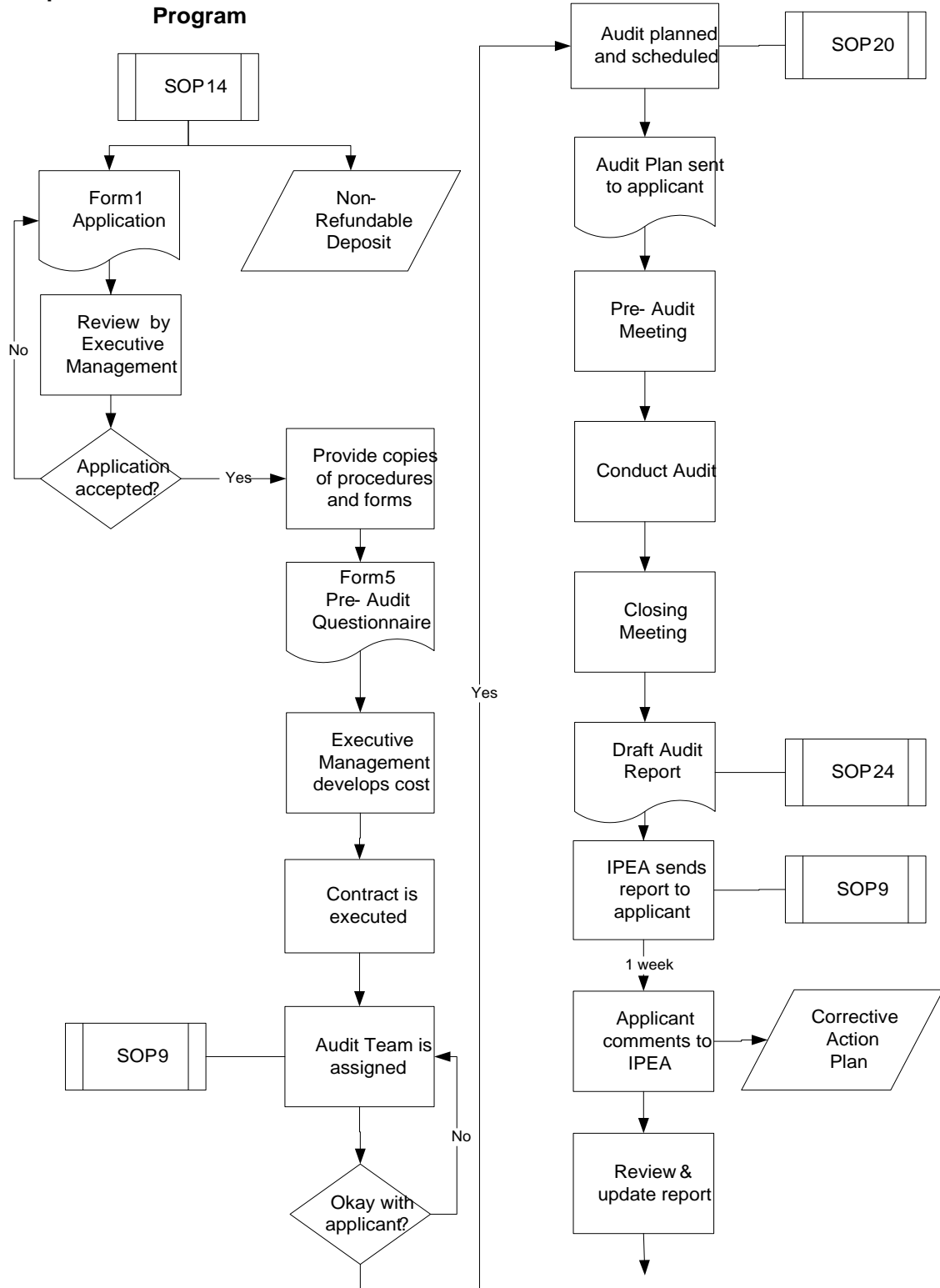
Upon certification, IPEA:

- a. Issues a certificate to the applicant.
- b. Adds the name of the company, manufacturing location, date of the last site audit, and list of excipients covered by the certification to the IPEA website.
- c. Makes available for purchase with the agreement of the applicant, the audit report with a portion of the proceeds credited to the applicant towards the annual certification fee.

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FIGURE 1

## Excipient GMP Conformance Certification Program



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## FIGURE 1

